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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN: 1124758
Facility ID: 209668
Inspection ID #2096680005

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

October 26, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Lori Wise, Director of Operations
Georgetown University Medical Center at Ballston
3833 North Fairfax Drive
Arlington, Virginia 22203

Dear Ms. Wise:

A representative from the Commonwealth of Virginia, under contract to the Food and Drug Administration (FDA), inspected your facility on October 18, 2000. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards), as specified in Title 21, Code of Federal Regulations, Part 900.12.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings:

- **The system your facility has in place to communicate patient results is not adequate, in that it does not send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination, nor does it provide a written report of the mammography examination to the referring health care provider as soon as possible, but no later than 30 days from the date of the examination.**

- **Your facility failed to provide records to document that [redacted] met the requirement of being licensed by a State to practice medicine.**

- **Your facility failed to provide records to document that [redacted] met the requirement of being certified by an FDA recognized board or had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography.**

The specific problems noted above appeared on your MQSA Facility Inspection Report, issued to your facility at the close of the inspection. These problems are identified as Level 1 findings because they identify failures to comply with significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent violations of the law that may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA requirements; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, the following Level 2 findings were listed on the inspection report provided to you at the close of the inspection:

- **Your facility failed to provide records to document that [redacted] met the requirement of having a minimum of 40 CME credit hours of documented medical education in mammography.**

- **Your facility failed to provide records to document that [redacted] met the requirement of having initial experience in interpreting or multi-reading at least 240 patient mammographic examinations within a 6-month period.**

- **Your facility failed to provide records to document that [redacted] met the requirement of having a minimum of 60 CME credit hours of documented medical education in mammography.**

- **Your facility failed to provide records to document that [redacted] met the requirement of having initial experience in interpreting or multi-reading at least 240 patient mammographic examinations in a 6-month period.**

- **A processor performance test was not performed on each day that clinical films were processed before any clinical films were processed that day.**

- **The weekly image quality evaluation test was not performed for at least two weeks for the facility's mammographic unit.**

- **Three of the nine random mammographic reports reviewed did not contain an overall final assessment of findings.**

- **Your facility failed to maintain records to document the qualifications of all interpreting physicians. One of the nine randomly selected mammographic reports reviewed was interpreted by a physician who had no personnel records on file for review.**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.

- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to:

Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201
Attn: Nancy Rose
Compliance Officer

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,

Lee Bowers
Director, Baltimore District

cc: Manfred Gorisch, Radiation Safety Specialist
Bureau of Radiological Health
Division of Health Hazards Control
Department of Health
Main Street Station
1500 East Main, Room 240
Richmond, Virginia 23219

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091